

27



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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,845	10/18/2001	Fred Levine	023070-110910US	7736
20350	7590	05/03/2004	EXAMINER	
TOWNSEND AND TOWNSEND AND CREW, LLP			LAMBERTSON, DAVID A	
TWO EMBARCADERO CENTER			ART UNIT	
EIGHTH FLOOR			PAPER NUMBER	
SAN FRANCISCO, CA 94111-3834			1636	

DATE MAILED: 05/03/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

9/15  
**Office Action Summary**

Application No.

10/041,845

Applicant(s)

LEVINE ET AL.

Examiner

David A. Lambertson

Art Unit

1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 02 February 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-10,12-21 and 31-37 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-9 and 31-36 is/are allowed.
- 6) ☒ Claim(s) 10,12-15,18-21 and 37 is/are rejected.
- 7) ☒ Claim(s) 16 and 17 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Receipt is acknowledged of a reply to the previous Office Action, filed February 2, 2004.

Amendments were made to the claims. Specifically, new claims 36 and 37 were added.

Claims 1-10, 12-21 and 31-37 are pending and under consideration in the instant application. Claims 11 and 22-30 have been cancelled. Any rejection of record in the previous Office Action, mailed October 2, 2003, that is not addressed in this action has been withdrawn.

Because this Office Action only maintains rejections set forth in the previous Office Action and/or sets forth new rejections that are necessitated by amendment, this Office Action is made FINAL.

### ***Specification***

The disclosure is objected to because of the following informalities: the amendment incorporating US Application 09/522,376 must be updated to reflect its status as US Patent No. 6,448,045. Additionally, Figure 4 has panels A-D, but only a description for panels A and B; it would be remedial for Applicant to indicate that the immunohistochemistry corresponds to FIG 4(A-C)(as opposed to just A), and that the Western blot corresponds to FIG 4(D)(as opposed to B), as it appears from an inspection of the figures.

Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Art Unit: 1636

Claim 37 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. **This is a new rejection that is necessitated by amendment.**

Claim 37 recites the limitation "the method of claim 17" in the preamble of the claim. There is insufficient antecedent basis for this limitation in the claim. Specifically, one cannot reasonably ascertain if the claim is a method claim (dependent on some claim other than claim 17), or if the claim is a product claim that is dependent on the culture of claim 17.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 10 and 21 remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 112***

Applicant's arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicant traverses the rejection by providing a declaration from a previous patent application, 09/522,376 (now US Patent 6,448,045), to which the instant application does not claim priority; this mandates that the two applications, should they both mature into patents, will

Art Unit: 1636

have different patent terms based on their different filing/priority dates. While the declaration indicates that cells in question (Blox5) were deposited, and the restrictions to the availability of the cells will be irrevocably removed upon the issue of the 09/522,376 application, and that the cell line will be maintained for at least 30 years after the date of the deposit or during the enforceable life of the patent, the declaration does not reference the instant application. As such, no guarantees are made regarding the availability of the cells with regard to the instant application, should the 6,448,045 patent term lapse. This is exceptionally important in the instant case with regard to 37 CFR § 1.806, regarding the availability of the strain; because the instant application and the application referred to in the declaration have different patent terms, the public availability of the strains (with regard to the instant application) will be below the minimum requirement as set forth in 37 CFR § 1.806. For these reasons, the declaration is insufficient to overcome the instant rejection. It would be remedial to provide a new declaration clearly referring to the instant application number.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 12-15 remain rejected under 35 U.S.C. 102(b) as being anticipated by Egan (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 102***

It is noted that the instantly rejected claims are drawn to products, and not methods. As such, only Applicant's arguments with regards to the product (i.e., the cultures/cells) will be addressed below, owing to the fact that the method claims are no longer rejected under 35 USC § 102(b), making such arguments moot.

Applicant's arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicant provides the following grounds of traversal:

1. Egan does not specifically teach the co-transfection of NeuroD/BETA2 and IDX-1 (i.e., PDX-1) into non-insulin producing cells, but merely states that one or more of three genes (where E27 was the third gene) can be transfected into such cells. Applicant argues that there is nothing to indicate that the specific combination of NeuroD/BETA2 and IDX-1 would be any better than any of the other combinations, therefore Egan does not teach a cell culture expressing both a recombinant NeuroD/BETA2 and IDX-1 (see for example pages 9-10, the bridging paragraph of Applicant's Arguments).
2. Egan does not teach the use of  $\beta$  cells, and their co-transfection with NeuroD/BETA2 and IDX-1 (see for example pages 10-11, bridging paragraph of Applicant's Arguments).

Applicant's arguments are not found convincing for the following reasons:

1. The fact of the matter is that Egan teaches pancreatic cells that are co-transfected with both NeuroD/BETA2 and IDX-1. Applicant recognizes that the combination of cells co-transfected with both NeuroD/BETA2 and IDX-1 is contemplated in the specification of Egan, but argues that there would be no motivation to choose these cells as opposed to the other 5 possibilities (it

Art Unit: 1636

is noted that there are 7 possibilities, 2 of which comprise both NeuroD/BETA2 and IDX-1). However, Applicant's argument that there is no indication that one particular combination of recombinant genes is misplaced in an argument of anticipation. Because there is no need for a motivation to select one cell type over the other, and because Egan recites two combinations that satisfy the limitations of the stable culture of cells that is indicated in claims 12-15 (i.e., the co-transfection of NeuroD/BETA2 and IDX-1), Egan anticipates the claims. Regarding the response of said cells to GLP-1 or GLP-1 analogs/orthologs, these cells must inherently possess such a response, or the instant invention would be inoperable. Indeed, the recognition of this fact by Egan is implicit in the specification and the Abstract, where Egan contemplates contacting the cells described in their specification with GLP-1 and analogs such as Exendin-4.

2. It is noted that the instantly rejected claims are directed simply to pancreatic cells, and not  $\beta$ -cells, specifically. Egan clearly anticipates the use of non-insulin producing pancreatic cells (such as pancreatic acinar cells) in their specification, thereby satisfying the minimum limitation in each of the rejected claims.

In conclusion, Applicant's arguments that Egan does not anticipate the instantly rejected claims are unconvincing. Contrary to Applicant's assertion, there is no need to select one particular set of cells out of each of the cell types that Egan teaches; the simple fact is that Egan teaches cells that anticipate the instant claims. Additionally, there is no limitation in the instantly rejected claims that requires the cells to be  $\beta$ -cells, thus that grounds for traversal is moot. As a result, the instant claims remain rejected for the reasons set forth in the previous Office Action.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 18 and 19 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Egan in view of Levine (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

Claim 20 remains rejected under 35 U.S.C. 103(a) as being unpatentable over Egan in view of Levine, and in further view of Baetge (as cited in the previous Office Action). **This rejection is maintained for the reasons set forth in the previous Office Action.**

***Response to Arguments Concerning Claim Rejections - 35 USC § 103***

Applicant's arguments filed February 2, 2004 have been fully considered but they are not persuasive. Applicant has provided the following collective grounds of traversal regarding the two rejections under 35 USC § 103(a) indicated above: Applicant asserts that Egan does not teach all of the elements of the rejected claims, and that neither Levine nor Baetge address the deficiencies of Egan, therefore the combination of references cannot make the instantly claimed rejection obvious (see for example page 11, last paragraph of Applicant's Remarks).

Applicant's arguments have been fully considered but are not found persuasive.

Applicant's arguments will be addressed collectively with regard to both rejections under 35



Art Unit: 1636

USC § 103(a), as in the manner in which they are presented. First, as set forth above in response to Applicant's traversal of the rejection under 35 USC 102(b), Egan does indeed anticipate claim 12. Thus, there are no deficiencies in the teachings of Egan as it regards the independent claim 12, from which claims 18-20 depend. As such, Applicant's allegation that neither Levine nor Baetge remedy the deficiencies of Egan with regard to the independent claim is moot. Furthermore, Applicant provides no arguments regarding the motivation or obviousness to combine the references, therefore the Office must presume the motivation and obviousness statements provided in the previous Office Action are sufficient. As such, the rejection is maintained because the Office has provided teachings of each and every limitation of the claims, as well as an appropriate motivation and obviousness to combine the references.

***Allowable Subject Matter***

Claims 1-9 and 31-36 are allowed.

Claims 16 and 17 objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO**

Art Unit: 1636

MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Lambertson whose telephone number is (571) 272-0771. The examiner can normally be reached on 6:30am to 4pm, Mon.-Fri., first Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on (571) 272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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JAMES KETTER  
PRIMARY EXAMINER